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1 RECORD OF ORAL HEARING
2 UNITED STATES PATENT AND TRADEMARK OFFICE
3

4
5 BEFORE THE BOARD OF PATENT APPEALS
6 AND INTERFERENCES

7 *Ex parte* STEVEN T. BOYCE
8

9 Appeal 2008-4764
10 Application 10/092,237
11 Technology Center 1600

12 Oral Hearing Held: February 3, 2009
13

14
15 Before DONALD E. ADAMS, LORA M. GREEN, and MELANIE L.
16 McCOLLUM, *Administrative Patent Judges*.

17 ON BEHALF OF THE APPELLANT:

18 Beverly Lyman, Esquire
19 THOMPSON HINE, LLP
20 Intellectual Property Group,
21 P.O. Box 8801
Dayton, Ohio 45401-8801
22

23 PROCEEDINGS

24 MS. BOBO-ALLEN: Calendar No. 6, Appeal No. 2008-4764. Ms.

25 Lyman.

1 JUDGE ADAMS: Good morning, Ms. Lyman.

2 MS. LYMAN: Good morning.

3 JUDGE ADAMS: We're familiar with your record, and you'll have
4 20 minutes and you can begin when you're ready. And all I would ask is
5 that you start by spelling your name into the record and introducing your
6 colleague.

7 MS. LYMAN: Beverly Lyman, L Y M A N, for appellant; Dr. Steven
8 Boyce, S T E V E N B O Y C E, inventor. Thank you, and may it please
9 the Court, my job here this morning is to do three things, and I'm glad to
10 entertain questions along the way. I'd like to distinguish our claims over the
11 applied art that what we're calling the Niels reference for novelty and
12 obviousness, to demonstrate enablement, and then to word the claims
13 appropriately to distinguish over the art.

14 Our inventive device, the cultured -- what we call the cultured skin
15 device is used to treat burn patients basically. It's a matrix of collagen that is
16 fabricated so it's reticulated. The reticulations allow a dermal cell layer to
17 form a lamination to cover the matrix. The dermal cells don't go into pores
18 or channels and --

19 JUDGE ADAMS: But can they bury themselves into this collagen
20 matrix?

21 MS. LYMAN: I'm sorry, question?

22 JUDGE ADAMS: Can they bury, you know, dig into or enter into
23 this matrix?

24 MS. LYMAN: No, judge, they --

25

1 JUDGE ADAMS: Is there something in your spec that may
2 distinguish that here?

3 MS. LYMAN: Yes, because we, we talk about a support, a, a
4 substantial continuous surface support lamination layer. And we talk on
5 page -- I'll look for the page number as I speak. We talk that it is the surface
6 lamination layer that forms before the cells bury or get into the matrix. And
7 that's why we have the matrix with reticulations so it forms a netlike
8 structure the cells cannot penetrate, there is nothing to penetrate.
9 Eventually, the matrix will degrade and the cells will go into -- but that
10 support lamination layer of dermal cells is necessary for the epidermal cells
11 to go on top of that and to provide the barrier function. The basement
12 membrane function occurs quickly so the cells are not buried into the matrix
13 when that barrier function forms, when that basement membrane forms, and
14 the device can be engrafted at that point. So there are very few, if any, cells
15 in the matrix. Eventually, the cells do get into the matrix, but not, not
16 immediately so you can get that epidermal cell layer on top of that dermal
17 cell layer.

18 JUDGE ADAMS: Okay, and this is important that we, we discuss
19 this because this is one of the arguments that you use to distinguish the Niels
20 reference because I think Niels says you take your, your dermal cells and lay
21 it on to this matrix, and you see colonization of the matrix as well as
22 invasion of the cells into the matrix. Now, I think -- I also recall arguments
23 that you've made that said that there is no temporal arrangement in your
24 claim so that you can add the dermal cells and then later add the epidermal
25 cells. And there's no time period for when you do -- when you add the

1 epidermal cells to the, to the matrix. This whole idea about quickly you've
2 already distinguished as not being in your claim. So, the question would be
3 back to would the dermal cells invade your matrix? And if not, why not?

4 MS. LYMAN: Two things, judge. First of all, we can add the, the
5 distinction and we do have in some of our claims that the dermal cells are
6 first inoculated and then the epidermal cells are inoculated, and we would be
7 amenable to that. Your second question was why the dermal cells don't
8 invade the matrix?

9 JUDGE ADAMS: Yes.

10 MS. LYMAN: Because they can't. It's a net structure, there are no
11 pores. The dermal cells are on the surface, they form a surface lamination
12 there.

13 JUDGE ADAMS: So, your argument would be the only way they
14 could invade the, the matrix is if there are pores in the matrix?

15 MS. LYMAN: Correct, pores or channels as Niels has.

16 JUDGE ADAMS: So, if someone would report out in the literature a
17 reticulated matrix, how would that distinguish from your reticulated matrix?

18 MS. LYMAN: We define a reticulated matrix. We define it as not
19 having pores, not having channels, as having what we call substantially
20 uniform, symmetric reticulations. And that goes to our argument why it's an
21 engineered device, it is not a biologic. Ours is fabricated, ours is
22 reproducible, ours is precise. We form the same reticulations time after time
23 after time. We are not dependent on a biologic.

24 JUDGE ADAMS: Okay, so when you go to, for example, Claim 1,
25 we have this idea of an engineered bio-compatible reticulated acellular

1 matrix comprised of collagen. And the Examiner's position is well, that's
2 pretty broad in his, in his or her view because engineered could be anything
3 that a person does. And the reticulated acellular matrix, well, the prior art
4 talks about that and it's also comprised of collagen. And the Examiner's
5 position is what is it in your claim that distinguishes engineered bio-
6 compatible reticular or, or narrowly construes engineered bio-compatible
7 reticulated to something that's in your, in your Specification?

8 MS. LYMAN: Two things. Our definition of reticulations, we give it
9 a precise definition.

10 JUDGE ADAMS: Can you show me that in the spec?

11 MS. LYMAN: Yeah, I can.

12 JUDGE ADAMS: And this time, I'm going to hold you to showing
13 me the page.

14 MS. LYMAN: I'm sorry, one more time?

15 JUDGE ADAMS: This time I'm going to hold you to showing me the
16 page.

17 MS. LYMAN: I, I will. Page 20. May I read?

18 JUDGE ADAMS: Please.

19 MS. LYMAN: Because the matrix is reticulated and, thus, contains
20 multiple continuous surfaces as opposed to being perforated with direct
21 channels or openings from the top surface to a bottom surface, the
22 fibroblasts, which are -- my, my addition -- which are dermal cells or other
23 dermal cells being inoculated need not fill these channels or openings in the
24 matrix before the epidermal cells may be added. Rather, upon inoculation,
25 the dermal cells attach to the reticulations and, thus, are able to provide a

1 continuous surface lamination for the subsequent inoculation of epidermal
2 cells within a shorter time period than is possible using a perforated matrix.

3 JUDGE ADAMS: The problem that I see with that is right there at
4 line 15, the dermal cells being inoculated need not fill these channels. It
5 doesn't say they do not fill these channels or openings in the matrix, they just
6 don't have to.

7 MS. LYMAN: They, they do not fill. They -- we have demonstrated
8 --

9 JUDGE ADAMS: But that's not what it says. It says it need not
10 which means they might and might not.

11 MS. LYMAN: Specification written seven years ago -- exactly, they,
12 they do not. We've demonstrated histological sections to examine -- in our
13 PowerPoint showing a surface lamination. They, they do not fill the
14 channels. So they do form the surface lamination and we have histological
15 proof of that, and so by the surface lamination --

16 JUDGE ADAMS: Just -- we have the PowerPoint slides, is there a
17 Declaration that goes along with that?

18 MS. LYMAN: There is.

19 JUDGE ADAMS: And that's of record?

20 MS. LYMAN: It is.

21 JUDGE ADAMS: Any directive on that in the brief?

22 MS. LYMAN: In, in the brief? The Declaration was filed July -- the
23 amendment following was filed July 20th.

24 JUDGE ADAMS: That would be your second Declaration?
25

1 MS. LYMAN: That would be our -- I believe it's our second or third
2 Declaration.

3 JUDGE ADAMS: Because I think the, the brief, if I recall correctly,
4 talks about a March 26,'04 Declaration which would be a first Declaration.
5 And an obvious second '05 -- oh, wait -- yes, an obvious first '05 Declaration
6 which would be a second Declaration. I don't recall the brief talking about a
7 third Declaration.

8 MS. LYMAN: There was a Declaration filed I want to say August 1,
9 2005.

10 JUDGE ADAMS: Right, correct, and that describes the PowerPoint
11 slides?

12 MS. LYMAN: No, I'm sorry, it distinguishes over art, the describing
13 bit, the surface lamination as, as opposed to a reticulated matrix with no
14 perforations.

15 JUDGE ADAMS: Can you show me where it specifically says they
16 do not -- your matrix does not have pores or would exclude dermal cells
17 from invading the matrix?

18 MS. LYMAN: In our August 1, 2005 Boyce Declaration, paragraph 4
19 distinguishing over other art. My Specification clearly distinguishes a
20 perforated --

21 JUDGE ADAMS: Right, that's what we just read --

22 MS. LYMAN: Okay.

23 JUDGE ADAMS: -- where it says need not.

24 MS. LYMAN: Well, no, this is a Declaration now.

25 JUDGE ADAMS: I agree.

1 MS. LYMAN: Okay.

2 JUDGE ADAMS: But the Declaration -- excuse me, the Declaration
3 cites to the Specification and says my Specification clearly distinguishes a
4 perforated matrix from a reticulated matrix and it self-provides support.
5 Why it is not obvious to substitute a perforated matrix for my matrix -- and
6 now, let's -- we have to recall this is all in the context, if I remember this
7 correctly, all in the context of prior art that talked about matrices that had
8 pores directly through them.

9 MS. LYMAN: Correct.

10 JUDGE ADAMS: It's not in the context of a prior reference like Niels
11 which says I have a reticulated matrix, and where in the distinction that
12 you're making against Niels and your invention is that, well, Niels talks
13 about the dermal cells invading the matrix. So, to go on with what the
14 Declaration says, mine doesn't have perforations -- oh, okay -- and it need
15 not -- citing to the Specification which you just read into the record -- need
16 not -- the dermal cells need not fill channels or openings in the matrices. So,
17 the question is how are we distinguishing -- we're still back to how do we
18 distinguish your reticulated matrix from Niels's reticulated matrix if you
19 have not clearly demonstrated that dermal cells do not -- emphasis on the do
20 not -- invade your matrices?

21 MS. LYMAN: By several means, and that's only one of the
22 distinctions over, over Niels, and we would be glad to provide such a
23 Declaration if that would help. The other distinctions --

24 JUDGE ADAMS: Well, it's not going to help you today, right?

25 MS. LYMAN: Well, during re-prosecution.

1 JUDGE ADAMS: Right, right.

2 MS. LYMAN: The other distinctions were the engineered and, and --

3 JUDGE ADAMS: Okay, now show me in your Specification where
4 you say or use the word engineered.

5 MS. LYMAN: We do not use the word engineered, but we discuss --
6 we, we tell how to fabricate the matrix. So, although the word is not used,
7 the chemical procedures to fabricate, engineer, manufacture, not use a
8 biologic, and collectively, we had support for engineered, so we, we
9 amended the claims.

10 JUDGE ADAMS: Well, amending your arguments in your brief, you
11 say it's chemically engineered, is that right?

12 MS. LYMAN: It, it's chemically engineered, it's chemically
13 manufactured, it's chemically fabricated.

14 JUDGE ADAMS: So, wouldn't chemically manufactured or
15 something along the lines that this is a non-naturally occurring bio-
16 compatible reticulated acellular matrix, if, in fact, you do have support for
17 that, wouldn't that be better than saying engineered?

18 MS. LYMAN: Judge, I'm not sure what would be better at this point.
19 We are willing to work with, with acceptable -- or with suggestions for
20 claim language, but we, we've tried amending the claims at various points to
21 make that distinction unsuccessfully. Constructed as opposed to Niels's
22 deconstructed biologic where he's taking a biologic apart, we're
23 synthesizing, we're putting it together. So, yes, we can, we can further
24 clarify --
25

1 JUDGE ADAMS: Well, I think, I think what the Examiner -- I think
2 my read on what the Examiner's saying is yes, I appreciate the fact that you
3 have this, this embodiment in your Specification that talks about
4 manufacturing a, a matrices from, from some collagen soup, right. But that
5 doesn't necessarily mean that I have to read your claim to mean starting with
6 some collagen powder, stirring it up in a big vat, and forming a matrix. I
7 can, I can read your claim to say well, that's a naturally occurring matrix.

8 MS. LYMAN: Well, that's the Van Gruen argument. You know, are
9 you reading limitations from the, from the Spec into the claims or are you
10 interpreting the claims in light of the Specification? So, we're not having a
11 meeting of the minds with the Examiner. If we can, if we can have such a
12 meeting, we'll, we'll work with the claim language to convey that
13 fabrication, that construction.

14 JUDGE ADAMS: So, I'm not sure what you're asking me. Do you
15 want me to send the case back or --

16 MS. LYMAN: Of course, I'd like you to allow the case, but --

17 JUDGE ADAMS: Well, I can't do that either.

18 MS. LYMAN: Well, because of, of the, the differences, the, the
19 engineered, the matrix difference, let me just point to Niels, the primary
20 reference on page -- I'm sorry, 843 -- 845, the second column, middle of the
21 page that Niels discloses that it could not get a lamination layer. It got
22 clumps of dermal cells. So, there --

23 JUDGE ADAMS: Where would -- show me what line is that?

24

25

1 MS. LYMAN: It's the, the paragraph one, two, three, four above the
2 discussion section of Niels. And it begins with the bolded Human Reticular
3 Second-Cut Dermis.

4 JUDGE ADAMS: Yes, how many lines, how many lines down in that
5 paragraph?

6 MS. LYMAN: If you read the first 1, 2, 3, 4, 5, 6, 7, 8, 7 or 9 lines
7 with the sentence starting about midway through that paragraph,
8 "conditioning the surface with either fibronectin or collagen did not enhance
9 keratinocyte attachment seeding culture dermal fibroblasts on second-cut
10 dermis resulted in both colonization, i.e., not lamination, on the surface as
11 well as invasion of the acellular dermis." So, it's not just being reticulated,
12 it's the engineered, it's the lamination. We're trying to choose claim
13 language that clearly conveys the differences.

14 JUDGE ADAMS: I, I feel like I have to ask, you're defining
15 colonization as something separate than lamination?

16 MS. LYMAN: Yes.

17 JUDGE ADAMS: What is colonization?

18 MS. LYMAN: Clumps.

19 JUDGE ADAMS: And what is lamination? You're saying it's
20 something that's spread out over the entire matrix?

21 MS. LYMAN: We have support for the continuous surface.

22 JUDGE ADAMS: Why would you interpret colonization as clumps
23 based on Niels's disclosure?

24 MS. LYMAN: What, what Niels is conveying that it was not a, a
25 covering.

1 JUDGE ADAMS: Where does he say it's not a covering? He says
2 it's colonization of the surface. And while you're looking for that, I just want
3 to make sure I'm clear. Niels is this author's first name, is that right?
4 Typically we use the author's last name. We're using the author's first name,
5 is this --

6 MS. LYMAN: But the Examiner had started to use
7 it --

8 JUDGE ADAMS: I understand.

9 MS. LYMAN: -- so we kept it for ease. Just the word colonization,
10 if, if you look at microbial colonies, they're discrete, they're not covering the
11 surface. It's, it's not a, a smooth, continuous layer of cells. It's on, it's in,
12 and we're also trying to make that distinction. Before my time runs out, may
13 I also address enablement?

14 JUDGE ADAMS: Actually, I don't think we have too much of a
15 problem with the 112 issues before us. I think that your best bet would be to
16 -- with the priority at this point for us.

17 MS. LYMAN: Okay.

18 JUDGE ADAMS: We're having the biggest difficulty -- we, we
19 clearly understand the issue on the 112 issues. We're not having too much
20 of a problem. We're having a problem with your arguments against the prior
21 art, is that fair?

22 JUDGE GREEN: And, and the claim language that you're using
23 because you're trying to have us define it in a very specific way without
24 really -- you know, we are, we are -- our mandate is to give claims the
25 broadest possible interpretation so we can clear up any issues now.

1 MS. LYMAN: I'm sorry, was there a question?

2 JUDGE GREEN: No, I'm just saying, I mean, you, you're asking us
3 to read a lot into these claims, but our mandate is to give the claims their
4 broadest reasonable interpretation. And you're asking us to limit engineered
5 to a specific embodiment in your Specification, you know. It, it -- we're
6 really trying to find something that --

7 MS. LYMAN: And we are, too, the language that would allow us to
8 appropriately distinguish the engineered, we thought, the chemically
9 engineered, chemically constructed. If needed, we can talk about the
10 formation from a cast-frozen dehydrated collagen-containing solution or
11 protein-containing solution. If that would be acceptable, we would be glad
12 to so amend the claims, all the claims to distinguish that. We're just at a
13 point where we're not sure what language would be acceptable to distinguish
14 over the art.

15 JUDGE GREEN: See, that is, that's something that is hard for us to
16 do because we don't do prosecution. Have you tried having an interview
17 with the Examiner as well as the, the bio-tech practice specialist?

18 MS. LYMAN: We have had three interviews with, with the
19 Examiner.

20 JUDGE GREEN: Would the -- but you could also ask to have an
21 interview with the bio-tech practice specialist present at the interview.

22 MS. LYMAN: At the, at the beginning of prosecution, it was with the
23 Examiner and the primary Examiner. No, Judge, we haven't tried that. If, if
24 you believe that would help, we would be glad to do that.

25

1 JUDGE GREEN: Because we cannot tell the Examiner that this
2 language would be -- all we can do is review the claim language in front of
3 us and review the evidence of record and say yes, this rejection is good or
4 no, this rejection has to fall for these reasons. So, we can't, we can't sit here
5 and, and suggest claim language to you. We understand your frustration, but
6 our role is just reviewing the rejection before us.

7 MS. LYMAN: Well, if, if you said to address -- not to worry about
8 the enablement rejection, that's fine. Concentrate on the art rejection, then
9 we will go back and do that, and, and so request an interview and work out,
10 hammer out acceptable claim language to distinguish over Niels. There is --
11 should, should I address the obviousness rejection?

12 JUDGE ADAMS: Please.

13 MS. LYMAN: Okay. Niels is the primary reference again, so
14 obviously that was the main art, but then the combination of two of Dr.
15 Boyce's publications, a, a previous patent which had a non-cellular
16 lamination layer, so, again, the cellular versus an acellular lamination layer
17 would distinguish, and then another publication which was simply an
18 overview of the art at, at the time of filing -- time of publication, 1998,
19 which did not disclose this at all. So, it comes down to the combination
20 would not render this obvious because the cellular lamination layer that
21 we're trying to claim was not disclosed in Niels or the 1999 patent applied in
22 the obviousness rejection. So, again, we're relying on the cellular lamination
23 layer engineered to have robust meaning in the claims. On versus in, you
24 know. It's a subtle distinction, but yet each and every word in the claim is
25

1 supposed to have weight and meaning. We're, we're giving it that weight
2 and meaning.

3 JUDGE ADAMS: I appreciate the fact -- I saw the arguments about
4 on and I appreciate those arguments, but it would seem that Niels also
5 deposits the cells on the matrix --

6 MS. LYMAN: Again, not to --

7 JUDGE ADAMS: -- while, while the cells also invade. That's where
8 we came back to our discussion not really seeing anything from our
9 discussion or from my independent review of the record that would suggest
10 that yours necessarily excludes these cells from invading into the matrix.

11 MS. LYMAN: That's the temporal component. You know, after a
12 while they do invade the matrix because the matrix breaks down, but it's not
13 -- it's without a lamination layer. So, again, we're going to those few select
14 claim words that we're giving specific meaning to to distinguish the primary
15 reference.

16 JUDGE ADAMS: Well, this is interesting because you're saying it's
17 temporal. Now, you have a collagen matrix, Niels has a collagen matrix.
18 Your, your argument is you arrive at these matrices differently, right? Yours
19 is engineered chemically through some particular procedure, and Niels
20 extracts it and does some manipulations from cadaver skin.

21 MS. LYMAN: Well, the device versus a biologic argument, too.
22 We're still relying on that. It's a device.

23 JUDGE ADAMS: Okay. You both have these matrices. What's the
24 difference between these matrices? Let's come back to, I guess, the more
25 fundamental. Let's get away from all this engineered and all this fuzzy

1 language and say you have a collagen matrix, Niels has a collagen matrix.
2 His is extracted right from skin and the cell layer is removed. You have a
3 collagen matrix, he has a collagen matrix. What's the difference between
4 yours and his, just fundamental -- maybe you can help us on this --
5 fundamental biology, what's the difference between these matrices?

6 DR. BOYCE: May I speak?

7 JUDGE ADAMS: Absolutely.

8 DR. BOYCE: All right. The difference is that the natural tissue is
9 more dense and it has a basket weave- type of a structure. So, it has
10 channels that go from one side to the other. Particularly in this reference,
11 they take not the surface layer of the skin, but they actually take what is
12 called a second cut of the dermis. So, it's the deep dermis and it is a woven
13 material essentially. The dermis of the skin, the collagen component of the
14 dermis of the skin, is a woven structure.

15 JUDGE ADAMS: You can actually even use the board if that will
16 help you.

17 DR. BOYCE: Okay. So, dermis is a woven structure that in three
18 dimensions would have, would have at some point channels that would
19 allow continuity from one side to the other, and the density of this material is
20 much higher. So by comparison with our material, which is a specifically
21 structured reticulated matrix so there are no channels from side to side, this
22 material has a density of about one milligram per square centimeter. By
23 comparison, the dermis has a density of approximately ten-fold higher or
24 greater than -- ten-fold higher, greater than 10 milligrams per square
25 centimeter.

1 JUDGE ADAMS: So, when Niels speaks to a second-cut layer that is
2 reticulated, in your words, what does that mean?

3 DR. BOYCE: Well, reticulated means interconnected, right. So, a
4 woven structure can be interconnected, the, the fibers are interconnected.
5 They're laid over each other, but they have channels that go from one side to
6 the other. This material has interconnected sheets that are continuous so
7 there is no path from one side to the other. So, when the cells arrive on the
8 surface, they fall on to the surface and then the continuity of the surface is
9 established by the interconnected sheets. So, that's what makes this a
10 nonporous material. By comparison, when the cells are put on to the -- this
11 is actually much higher density of material -- when the cells arrive on to the
12 natural dermis, it can travel down through the interconnected weavings and
13 go down into the sponge and even go out the other side perhaps, depending
14 on, you know, the specific channels that are, that are available. So, that's --
15 that difference in structure allows the cells to form this continuous
16 lamination versus being able to fall through the material or into the material
17 with the result being that if some of the cells are actually in the material and
18 some of the cells are on the material, you can get partial coverage as
19 opposed to continuous coverage across the surface. So that is the distinction
20 between a colony, a colonization, where it, it's a -- this is a perforated
21 matrix, a natural matrix is perforated. So you put a population there and
22 some of them drain down and you get a residual population on the top that
23 can make a colonization versus this has no perforations. So you put the
24 same population there and you get a continuous colonization, so that's the
25 structural difference. Then bio-chemically also this material is designed to

1 have a, a degradation time which is necessary or desirable for surgical
2 application of about two to four weeks after transplantation. And then about
3 another two weeks prior to transplantation -- so this is post- and then pre- --
4 would be maybe about another two, two weeks, and that's in order to dispose
5 of the matrix and let the cells reform the tissue because the matrix is not
6 really the active component, it's the cells. Here the degradation time is, you
7 know, many months.

8 JUDGE ADAMS: I think that's a really great start for us to finish up
9 our discussion because now we go back to Claim 1. Now we have prior art
10 reference, Niels, and that's on the left, you maybe put a big N over the Niels
11 disclosure. What, what is it in your claim that distinguishes Niels from --
12 I'm sorry, I was stumbling over Boyce, apology.

13 MS. LYMAN: Two words, device lamination.

14 JUDGE ADAMS: Okay, well, the problem with the word device for,
15 for me is as soon as Niels takes that cadaver skin, takes the cells off it and
16 reseeds it, he has a device, right?

17 MS. LYMAN: Yes, a biologic.

18 JUDGE ADAMS: Well, why wouldn't yours also be a biologic?

19 MS. LYMAN: Synthesized, fabricated, again, it's, it's --

20 JUDGE ADAMS: It's fabricated out of collagen, right?

21 MS. LYMAN: It's -- we're constructed, his is deconstructed.

22 JUDGE ADAMS: Dr. Boyce?

23 DR. BOYCE: If I can make a comment.

24 JUDGE ADAMS: Please.

25

1 DR. BOYCE: There are, there are related products that are actually in
2 the marketplace, and there is an acellular allergenic human dermis that's
3 available, and it's available as a banked tissue. There are other collagen
4 matrices that are available commercially for a variety of applications, and
5 those are medical devices and that, that's not necessarily directly related to
6 the patent situation. But there are distinctions that are made at the regulatory
7 level because of the fact that the other thing is that this has reproducibility
8 which is based on the fabrication, whereas, this is biologically derived so
9 there are no two pieces that are exactly the same. So that's another
10 distinction in the composition of the material that allows this to be a device
11 and this to be a biologic because this can have predictable reproducibility of
12 structure, of composition, and this cannot just by definition, inherent
13 definition, because this comes from different areas of the body. You have
14 different densities of weave, some skin is softer, some skin is tougher --

15 JUDGE ADAMS: I understand, I understand.

16 DR. BOYCE: -- age, different sources, different individuals.

17 JUDGE ADAMS: Is there a Declaration or something on the record
18 to say that Niels is a perforated matrix just because it has to be because it's
19 naturally obtained?

20 MS. LYMAN: That exact wording, that exact sentence I don't know.
21 I'll have to --

22 JUDGE ADAMS: Okay, anything close?

23 MS. LYMAN: Yeah.

24 JUDGE ADAMS: Okay, show me.

25 MS. LYMAN: Several. Okay, so the question is --

1 JUDGE ADAMS: The question is why is -- the
2 question -- let me take a moment. The question is Niels cannot be the
3 reticulated matrix according to your claimed invention as you define
4 reticulated matrix because Niels has pores. Because it is a naturally obtained
5 matrix, it has pores that travel from one side to the other whereas yours does
6 not. If I recall correctly, during prosecution I believe the Examiner with
7 three references that were references that taught matrices with pores, is that
8 correct, h e withdrew the application of those references as prior art?

9 MS. LYMAN: He never, he never applied those references and
10 withdrew others, so Wilkins is correct, yes.

11 JUDGE ADAMS: So, it seems to me that if we can distinguish Niels
12 as a natural product that has pores just -- it does, and there's evidence to
13 support that and there's evidence to support that yours does not have pores, I
14 think that would distinguish your claimed invention, no?

15 MS. LYMAN: Well, I will direct you to our amendment filed on
16 January 26, 2006, page 15 --

17 JUDGE ADAMS: Wait, wait, wait, wait --

18 MS. LYMAN: I'm sorry.

19 JUDGE ADAMS: They're taking me off of the record --

20 MS. LYMAN: Oh, I'm sorry, it's against those other two, it's against
21 the other two -- three references not applied raised during the interview.

22 JUDGE ADAMS: Is it in a Declaration? If, if you're going to take
23 me to an amendment, then I'm going to tell you, well, that's Attorney
24 argument.

25 MS. LYMAN: It, it's the August 1, 2005 Declaration of Boyce.

1 JUDGE ADAMS: Okay, I can do that.

2 MS. LYMAN: But it's not directed to Niels, it's directed to these three
3 other references that do have pores.

4 JUDGE ADAMS: Well, the problem that I have to -- the problem that
5 we're going to have is that I need something on the record that would tell me
6 that Niels is, is a matrix that's obtained from skin, and, therefore, it
7 necessarily has pores in it because it just does. It's a product of nature and a
8 product of nature would be expected to have pores in it, or it would not even
9 be expected, it wouldn't necessarily have pores through it.

10 MS. LYMAN: We, we say that Niels has pores. We say that ours
11 doesn't have pores. We do not have one Declaration that says Niels has
12 pores, ours doesn't have pores.

13 JUDGE ADAMS: Where do you say in the Declaration that Niels has
14 pores?

15 MS. LYMAN: In the Declaration that Niels has pores?

16 JUDGE ADAMS: I mean if you're going to say Niels has, Niels has
17 pores, then that gets back to the Attorney argument. If you're saying Niels
18 has pores in an amendment, I need something that's going to support that,
19 either a Declaration, some reference, some evidentiary basis to support that.

20 MS. LYMAN: Well, if we don't, we will give it to you.

21 JUDGE ADAMS: I mean that makes sense, right? I mean am I going
22 off on a tangent here meeting a standard? If you, if you have Dr. Boyd's --
23 or Boyce's, excuse me, matrix and you've defined that matrix as not having
24 pores and you've actually locked that down in your Specification just as he's
25 drawn it here on the board, and he can walk in and say everybody knows

1 that collagen from skin has pores in it, I mean that's universal. Then don't
2 you think that would help you?

3 MS. LYMAN: We also thought that the fabricated, we thought that
4 the freeze-thaw, we thought that the purified collagen, the generation would
5 also help us. So, if you say that that would be the most helpful, we will give
6 it to the Examiner.

7 JUDGE ADAMS: It seems like that would be a fair argument to me,
8 but where in your Specification does it say that yours does not have pores?

9 MS. LYMAN: It's -- that, that one paragraph that I read before.

10 JUDGE ADAMS: Page 29 around 15 is what you cited --

11 MS. LYMAN: Page 20, line --

12 JUDGE GREEN: I mean but you don't -- I mean it's a mushy
13 paragraph because it starts without being bound by specific -- mechanism
14 the following event's likely to occur. I wish there was a better statement
15 than the way, you know --

16 MS. LYMAN: Because the matrix is reticulated and thus contains
17 multiple continuous surfaces as opposed to being perforated --

18 JUDGE ADAMS: Well, I mean we can't rely on reticulated because
19 both Niels and your invention is reticulated. That's not going to -- that word
20 in and of itself is not going to help you.

21 MS. LYMAN: But -- point taken, and we will, we will so make these
22 Declarations. My point is that we have defined reticulation in a certain way.
23 Just because Niels has used the same word --

24 JUDGE ADAMS: I agree with that.

25 MS. LYMAN: -- to define something differently --

1 JUDGE ADAMS: I agree with that. And what -- the problem that
2 you're, you're running into, at least in front of us, is that you keep pointing us
3 to page 20 of your Specification and this particular paragraph which Judge
4 Green just said is pretty mushy. It's not locking down your matrix in such a
5 tight way as to weed out the possibility that it has a pore in it.

6 MS. LYMAN: Well, and, and we were trying to do that with the
7 lamination argument. So, if the pores argument is better than the lamination
8 argument, we will so provide that Declaration.

9 JUDGE GREEN: I would also focus on -- I mean if we had
10 something in there that one of -- you know, in the Declaration for one of
11 ordinary skill in recolonization as going through the pores and not having
12 the lamination, I mean we can't predict when -- if you go back to the
13 Examiner what's going to happen. I do think that if you're focusing on these
14 words, you need to come in with some kind of evidence in the form of a
15 Declaration or something else that one would read colonization as this, these
16 discrete little colonies as opposed to lamination where you have this film.

17 MS. LYMAN: We will so do that then.

18 JUDGE GREEN: But we're, we're just -- we're trying to find it in
19 your Specification. We're not seeing the language the way that you would
20 like us to read it.

21 JUDGE ADAMS: I think that's a fair statement.

22 MS. LYMAN: And, and if, if you think that with an interview with
23 the bio-tech specialist would be an acceptable way to proceed?

24 JUDGE GREEN: I think a bio-tech specialist gives you a party who's
25 not been involved all the way through prosecution and may help both you

1 and the Examiner take that step back that you need and approach it in a way
2 and maybe work as, you know, as an arbitrator, a language that would be
3 mutually acceptable to both parties.

4 MS. LYMAN: That, that was my third point this morning, to try to
5 work out acceptable plain language. We will do that in prosecution.

6 JUDGE ADAMS: This is a great -- I mean with that, with that
7 meeting, this is a great starting point. This is what the prior art is, this is
8 what mine is. Somehow there's something here possibly, we just need to
9 figure out what the appropriate language is that gets us away from Niels
10 towards this, right. And if we can -- if you can sit down, perhaps draw this
11 out on a white board over in the Corps, and say this is what we have and we
12 have support for that, but you've got to have the support for it. And this is
13 what's going on with the prior art, now it's just a matter of what kind of
14 language is comfortable to both parties to get this case through
15 the -- right? We've gone way over and that's okay, but I, I need to start
16 wrapping up soon.

17 MS. LYMAN: A couple points, number one, thank you. That is an
18 acceptable way to proceed. Number two, when we did provide the
19 PowerPoint, we showed the surface lamination layer and we showed on, not
20 in. Tying a specific figure that is in the record that we've shown to this
21 specific reference was done in an amendment. If, if it requires a Declaration
22 to put -- to marry these two, we will provide it, but for the record, we have
23 shown that ours doesn't have pores. It's on, not in. And in seven years of
24 prosecution, we've gone through different art. So, focusing on Niels now,
25 focusing on the specific noun or verb that would be the make-or-break is

1 fine. We will continue to work on it, but it has been a, a chore to determine
2 which is the, which is the most problematic.

3 JUDGE ADAMS: I, I totally understand where you're coming from.
4 I mean at least two of the three of us were Examiners. The problem that
5 you're having with this whole idea of claim construction is you're in the
6 wrong venue. All we -- we're stuck with what we have, and we feel your
7 pain and we understand and we empathize. It's -- you're in the wrong venue.

8 MS. LYMAN: Well, with your guidance, we will attempt to work out
9 acceptable claim language to the Niels reference. Thank you for telling us to
10 focus on that and not enablement and the other 112 issues. So, it will be the
11 102 and the 103.

12 JUDGE ADAMS: Okay, thank you for your time.

13 MS. LYMAN: Thank you.

14 JUDGE ADAMS: And thank you for the -- thank you for doing that,
15 sir.

16 DR. BOYCE: It made the whole trip worth it.

17 (Whereupon, the hearing concluded at 10:14 a.m., on February 3,
18 2009.)
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